



59th Medical Wing



59th Clinical Research Division Research Day Briefing

Colonel Linda Steel-Goodwin
Director, 59 CRD
27 Oct 16



Agenda



Warrior Medics – Mission Ready – Patient Focused

- 59th Clinical Research Division (59 CRD) Mission



1255 Wilford Hall Loop, Bldg 4430

- Organization
- Funding
- CRD Capabilities
- POCs



59 CRD Mission



Warrior Medics – Mission Ready – Patient Focused

The 59 CRD provides centralized admin, technical, and scientific support and regulatory oversight and guidance to researchers in the development, performance, and dissemination of clinical investigations.

CRD directly supports wing readiness and certification training requirements for **residents, fellows, nurses, allied healthcare professionals, and providers.**

Four Focus Areas:

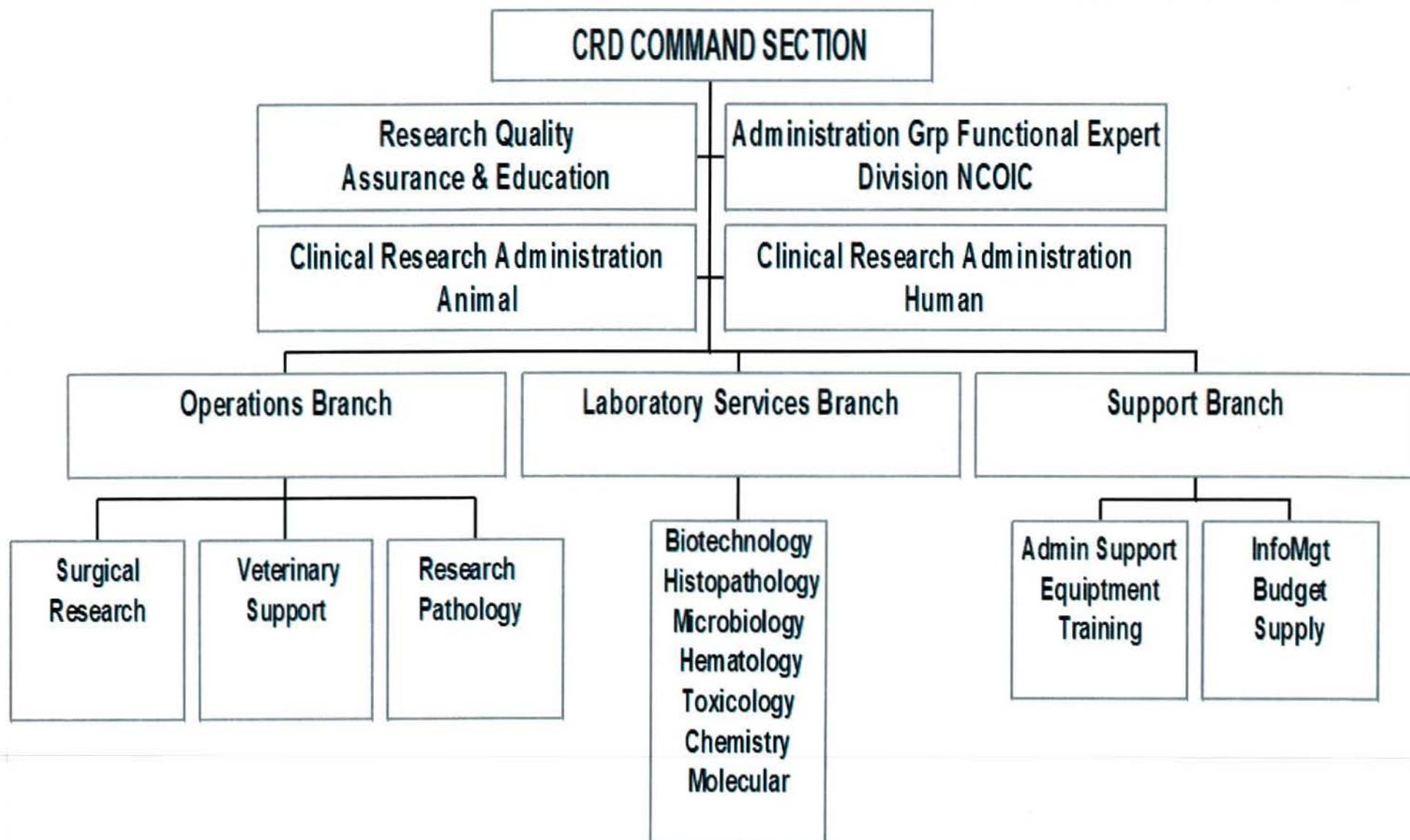
1. Clinical Investigation Support
2. Training
3. Support of RDT&E protocols
4. Research Subject Protection
 - Human Subjects: IRB – Institutional Review Board
 - Animal Subjects: IACUC – Institutional Animal Care and Use Committee



CRD Organization



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CRD Staff Expertise



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- 1 – DVM, Board Certified American College of Lab Animal Medicine; Certified by American College of Veterinary Pathology
- 1 – PhD, Physiology/Biochem – Clinical Research Admin; Certified by Aerospace Medical Assoc; Certified in Hyperbaric Physiology
- 1 – ScD, Biostatistics/Epidemiology – Animal Research Admin
- 2 – PhD, Molecular Biology/Virology
- 1 – PhD, Chemistry
- 1 – PhD, Biochemistry
- 1 – PhD, Biology/Neurology
- 1 – DrPH, Public Health in Disease/Immunology/Occu. Health
- 1 – DHSc, Health Science; Licensed Physician Assistant
- 10 – Masters Degrees in various disciplines



CRD Research Funding



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Accessing CRD Funding (SG5 CIP Program):

- Funding Level: **\$15K-\$30K** ... may fund at higher levels on a case-by-case basis; GME funding is 1-year money
- Part of Protocol Approval Process
 - PI asks for funding
 - 1st come, 1st served basis
 - Have quarterly targets, but they are not etched in stone
- Must have an Air Force Principal Investigator
 - Protocols may have Army/Navy AIs
 - Exception is Dental Post Graduate Program (WHASC Baseline)
- Baseline Cost covered for GHSE Publications, must request on Form 3039



Surgical Capabilities



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Three operating room suites:

- General and vascular surgery
- Orthopedic
- Ophthalmic
- Maxillofacial/dental
- Microsurgery

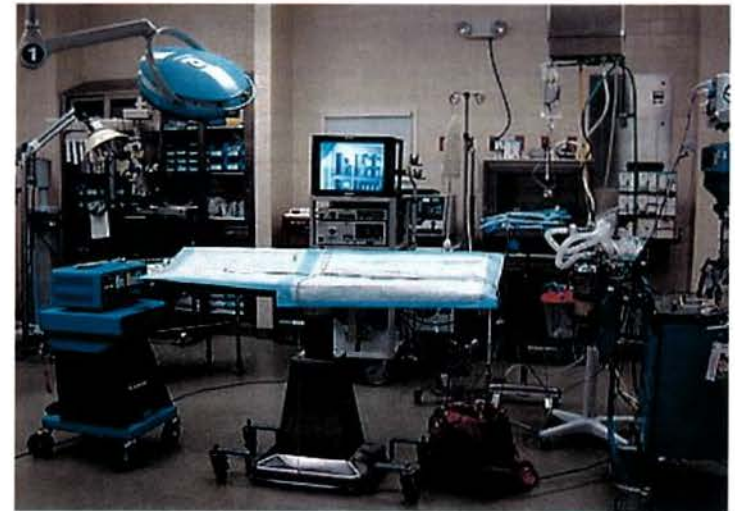
DaVinci robotic surgical system

Radiology (digital)

C-Arm (3)

Fluoroscopy

Ultrasound





Research Capabilities



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Clinical Laboratory

- Immunology
- Hematology/Chemistry

Instron Testing

- Determine fatigue, impact, and/or resistance of materials

Hyperbaric/Hypobaric Medicine

- Study aerospace physiology



Fully capable laboratory facilities

Expanded Toxicology Capabilities

- Highly specific
- Medical Toxicology studies
- Tandem Mass Spectrometer

Molecular Biology/Genomics

- Next Generation Sequencing
- Real Time PCR
- Multi-Plex Assays

Cell Biology

- Flow Cytometry

Microbiology

Coagulation and Hematology

Scanning Electron Microscope



CRD Website



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Home

Animal Research

CRD Capabilities

Calendar

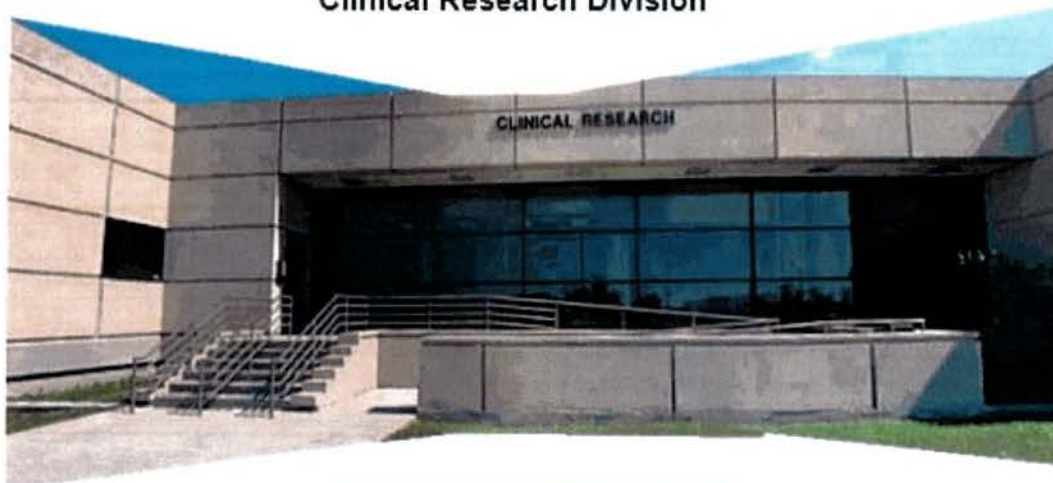
Funding

Points of Contact

Clinical Research

News

59th Medical Wing
Clinical Research Division



Calendar

CRD Capabilities

Human/Non-Human
Research

Clinical Research Division
Points of Contact

Animal Research

Current Research

News

<https://kx2.afms.mil/kj/kx8/ClinicalResearchJBSALackland/Pages/home.aspx>



59 CRD Points of Contact



Warrior Medics – Mission Ready – Patient Focused

IRB/IACUC Protocol Office

292-7143/6095/4012/4683

Ms. Rachel Montez – 292-4683

Rachael.Montez@us.af.mil

Publications and Presentations

292-7141; 59crdpubspres@us.af.mil

Human Studies

Dr. Rocky Calcote – 292-5203

rocky.calcote.1@us.af.mil

Animal Studies

Dr. Dawn Harris – 292-2771

linda.harris@us.af.mil

Statistics/Study Design/Funding

Dr. Anneke Bush – 292-7295

anneke.bush@us.af.mil

Laboratory Services Branch

Dr. Thomas Gibbons – 292-7363

Thomas.gibbons@us.af.mil

Pathology Section Support

LTC Michele Thompson – 292-6589

michelle.thompson.8@us.af.mil

Animal Scheduling

Mr. Todd Brown – 292-7709; todd.brown.9@us.af.mil

Research Education/Post-Approval Monitoring

Dr. Earl Grant – 292-5146; earl.grant.1@us.af.mil

Ms. Jennifer Palmer – 292-5819

jennifer.palmer.1.ctr@us.af.mil

Tours/Contracts/Concerns/Facilities Access

Chief – Col Steel-Goodwin – 292-7068

linda.steel_goodwin.1@us.af.mil

Deputy Chief – Paul Barnicott – 292-5687

paul.barnicott.1@us.af.mil



QUESTIONS/COMMENTS

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Thank You!





DEPARTMENT OF THE AIR FORCE
59TH MEDICAL WING (AETC)
JOINT BASE SAN ANTONIO - LACKLAND TEXAS

19 OCT 2016

MEMORANDUM FOR SGVUS

ATTN: COL LINDA STEEL-GOODWIN

FROM: 59 MDW/SGVU

SUBJECT: Professional Presentation Approval

1. Your paper, entitled 59th Clinical Research Division-Research Day Briefing presented at/published to 59 MDW Research Day, San Antonio, TX 27 Oct 2016 in accordance with MDWI 41-108, has been approved and assigned local file #16348.
2. Pertinent biographic information (name of author(s), title, etc.) has been entered into our computer file. Please advise us (by phone or mail) that your presentation was given. At that time, we will need the date (month, day and year) along with the location of your presentation. It is important to update this information so that we can provide quality support for you, your department, and the Medical Center commander. This information is used to document the scholarly activities of our professional staff and students, which is an essential component of Wilford Hall Ambulatory Surgical Center (WHASC) internship and residency programs.
3. Please know that if you are a Graduate Health Sciences Education student and your department has told you they cannot fund your publication, the 59th Clinical Research Division may pay for your basic journal publishing charges (to include costs for tables and black and white photos). We cannot pay for reprints. If you are 59 MDW staff member, we can forward your request for funds to the designated wing POC.
4. Congratulations, and thank you for your efforts and time. Your contributions are vital to the medical mission. We look forward to assisting you in your future publication/presentation efforts.

PAUL T. BARNICOTT, GS-15-DAF
Deputy Director Clinical Research Division

PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS

INSTRUCTIONS

USE ONLY THE MOST CURRENT 59 MDW FORM 3039 LOCATED ON AF E-PUBLISHING

1. The author must complete page two of this form:
 - a. In Section 2, add the funding source for your study [e.g., 59 MDW CRD Graduate Health Sciences Education (GHSE) (SG5 O&M); SG5 R&D; Tri-Service Nursing Research Program (TSNRP); Defense Medical Research & Development Program (DMRDP); NIH; Congressionally Directed Medical Research Program (CDMRP) ; Grants; etc.]
 - b. In Section 2, there may be funding available for journal costs, if your department is not paying for figures, tables or photographs for your publication. Please state "YES" or "NO" in Section 2 of the form, if you need publication funding support.
2. Print your name, rank/grade, sign and date the form in the author's signature block or use an electronic signature.
3. Attach a copy of the 59 MDW IRB or IACUC approval letter for the research related study. If this is a technical publication/presentation, state the type (e.g. case report, QA/QI study, program evaluation study, informational report/briefing, etc.) in the "Protocol Title" box.
4. Attach a copy of your abstract, paper, poster and other supporting documentation.
5. Save and forward, via email, the processing form and all supporting documentation to your unit commander, program director or immediate supervisor for review/approval.
6. On page 2, have either your unit commander, program director or immediate supervisor:
 - a. Print their name, rank/grade, title; sign and date the form in the approving authority's signature block or use an electronic signature.
7. Submit your completed form and all supporting documentation to the CRD for processing (59crdpubspres@us.af.mil). **This should be accomplished no later than 30 days before final clearance is required to publish/present your materials.** If you have any questions or concerns, please contact the 59 CRD/Publications and Presentations Section at 292-7141 for assistance.
8. The 59 CRD/Publications and Presentations Section will route the request form to clinical investigations, 502 ISG/JAC (Ethics Review) and Public Affairs (59 MDW/PA) for review and then forward you a final letter of approval or disapproval.
9. Once your manuscript, poster or presentation has been approved for a one-time public release, you may proceed with your publication or presentation submission activities, as stated on this form. **Note:** For each new release of medical research or technical information as a publication/presentation, a new 59 MDW Form 3039 must be submitted for review and approval.
10. If your manuscript is accepted for scientific publication, please contact the 59 CRD/Publications and Presentations Section at 292-7141. This information is reported to the 59 MDW/CC. All medical research or technical information publications/presentations must be reported to the Defense Technical Information Center (DITC). See 59 MDWI 41-108, *Presentation and Publication of Medical and Technical Papers*, for additional information.
11. The Joint Ethics Regulation (JER) DoD 5500.07-R, *Standards of Conduct*, provides standards of ethical conduct for all DoD personnel and their interactions with other non-DoD entities, organizations, societies, conferences, etc. Part of the Form 3039 review and approval process includes a legal ethics review to address any potential conflicts related to DoD personnel participating in non-DoD sponsored conferences, professional meetings, publication/presentation disclosures to domestic and foreign audiences, DoD personnel accepting non-DoD contributions, awards, honoraria, gifts, etc. The specific circumstances for your presentation will determine whether a legal review is necessary. **If you (as the author) or your supervisor check "NO" in block 17 of the Form 3039, your research or technical documents will not be forwarded to the 502 ISG/JAC legal office for an ethics review.** To assist you in making this decision about whether to request a legal review, the following examples are provided as a guideline:

For presentations before professional societies and like organizations, the 59 MDW Public Affairs Office (PAO) will provide the needed review to ensure proper disclaimers are included and the subject matter of the presentation does not create any cause for DoD concern.

If the sponsor of a conference or meeting is a DoD entity, an ethics review of your presentation is not required, since the DoD entity is responsible to obtain all approvals for the event.

If the sponsor of a conference or meeting is a non-DoD commercial entity or an entity seeking to do business with the government, then your presentation should have an ethics review.

If your travel is being paid for (in whole or in part) by a non-Federal entity (someone other than the government), a legal ethics review is needed. These requests for legal review should come through the 59 MDW Gifts and Grants Office to 502 ISG/JAC.

If you are receiving an honorarium or payment for speaking, a legal ethics review is required.

If you (as the author) or your supervisor check "YES" in block 17 of the Form 3039, your research or technical documents will be forwarded simultaneously to the 502 ISG/JAC legal office and PAO for review to help reduce turn-around time. If you have any questions regarding legal reviews, please contact the legal office at (210) 671-5795/3365, DSN 473.

NOTE: All abstracts, papers, posters, etc., should contain the following disclaimer statement:

"The views expressed are those of the [author(s)] [presenter(s)] and do not reflect the official views or policy of the Department of Defense or its Components"

NOTE: All abstracts, papers, posters, etc., should contain the following disclaimer statement for research involving humans:

"The voluntary, fully informed consent of the subjects used in this research was obtained as required by 32 CFR 219 and DODI 3216.02_AFI 40-402."

NOTE: All abstracts, papers, posters, etc., should contain the following disclaimer statement for research involving animals, as required by AFMAN 40-401_IP :

"The experiments reported herein were conducted according to the principles set forth in the National Institute of Health Publication No. 80-23, Guide for the Care and Use of Laboratory Animals and the Animal Welfare Act of 1966, as amended."

PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS			
1. TO: CLINICAL RESEARCH	2. FROM: (Author's Name, Rank, Grade, Office Symbol) LINDA STEEL-GOODWIN, COL, 59 MDW/SGV	3. GME/GHSE STUDENT: <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO	4. PROTOCOL NUMBER: N/A
5. PROTOCOL TITLE: (NOTE: For each new release of medical research or technical information as a publication/presentation, a new 59 MDW Form 3039 must be submitted for review and approval.) N/A			
6. TITLE OF MATERIAL TO BE PUBLISHED OR PRESENTED: 59TH CLINICAL RESEARCH DIVISION-RESEARCH DAY BRIEFING			
7. FUNDING RECEIVED FOR THIS STUDY? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO FUNDING SOURCE:			
8. DO YOU NEED FUNDING SUPPORT FOR PUBLICATION PURPOSES: <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO			
9. IS THIS MATERIAL CLASSIFIED? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO			
10. IS THIS MATERIAL SUBJECT TO ANY LEGAL RESTRICTIONS FOR PUBLICATION OR PRESENTATION THROUGH A COLLABORATIVE RESEARCH AND DEVELOPMENT AGREEMENT (CRADA), MATERIAL TRANSFER AGREEMENT (MTA), INTELLECTUAL PROPERTY RIGHTS AGREEMENT ETC.? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO NOTE: If the answer is YES then attach a copy of the Agreement to the Publications/Presentations Request Form.			
11. MATERIAL IS FOR: <input checked="" type="checkbox"/> DOMESTIC RELEASE <input type="checkbox"/> FOREIGN RELEASE CHECK APPROPRIATE BOX OR BOXES FOR APPROVAL WITH THIS REQUEST. ATTACH COPY OF MATERIAL TO BE PUBLISHED/PRESENTED.			
<input type="checkbox"/> 11a. PUBLICATION/JOURNAL (List intended publication/journal.)			
<input type="checkbox"/> 11b. PUBLISHED ABSTRACT (List intended journal.)			
<input type="checkbox"/> 11c. POSTER (To be demonstrated at meeting: name of meeting, city, state, and date of meeting.)			
<input type="checkbox"/> 11d. PLATFORM PRESENTATION (At civilian institutions: name of meeting, state, and date of meeting.)			
<input checked="" type="checkbox"/> 11e. OTHER (Describe: name of meeting, city, state, and date of meeting.) 59 MDW RESEARCH DAY, SAN ANTONIO, TX 27 OCT 2016			
12. HAVE YOUR ATTACHED RESEARCH/TECHNICAL MATERIALS BEEN PREVIOUSLY APPROVED TO BE PUBLISHED/PRESENTED? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO ASSIGNED FILE # _____ DATE _____			
13. EXPECTED DATE WHEN YOU WILL NEED THE CRD TO SUBMIT YOUR CLEARED PRESENTATION/PUBLICATION TO DTIC NOTE: All publications/presentations are required to be placed in the Defense Technical Information Center (DTIC).			
DATE TBD			
14. 59 MDW PRIMARY POINT OF CONTACT (Last Name, First Name, M.I., email) STEEL-GOODWIN, LINDA linda.steel_goodwin.l@us.af.mil			15. DUTY PHONE/PAGER NUMBER 292-7069
16. AUTHORSHIP AND CO-AUTHOR(S) List in the order they will appear in the manuscript.			
LAST NAME, FIRST NAME AND M.I.	GRADE/RANK	SQUADRON/GROUP/OFFICE SYMBOL	INSTITUTION (If not 59 MDW)
a. Primary/Corresponding Author STEEL-GOODWIN, LINDA	COL	59 MDW/SGV	
b.			
c.			
d.			
e.			
17. IS A 502 ISG/JAC ETHICS REVIEW REQUIRED (JER DOD 5500.07-R)? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO			
I CERTIFY ANY HUMAN OR ANIMAL RESEARCH RELATED STUDIES WERE APPROVED AND PERFORMED IN STRICT ACCORDANCE WITH 32 CFR 219, AFMAN 40-401_IP, AND 59 MDWI 41-108. I HAVE READ THE FINAL VERSION OF THE ATTACHED MATERIAL AND CERTIFY THAT IT IS AN ACCURATE MANUSCRIPT FOR PUBLICATION AND/OR PRESENTATION.			
18. AUTHOR'S PRINTED NAME, RANK, GRADE LINDA STEEL-GOODWIN, COL	19. AUTHOR'S SIGNATURE STEEL GOODWIN LINDA 1186463583		20. DATE 10/12/2016
21. APPROVING AUTHORITY'S PRINTED NAME, RANK, TITLE DR. DEBRA NIEMEYER, GS-15, 59 MDW CHIEF SCIENTIST	22. APPROVING AUTHORITY'S SIGNATURE NIEMEYER.DEBRA.M.1022593567		23. DATE October 12, 2016

PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS		
1st ENDORSEMENT (59 MDW/SGVU Use Only)		
TO: Clinical Research Division 59 MDW/CRD Contact 292-7141 for email instructions.	24. DATE RECEIVED 19 Oct 2016	25. ASSIGNED PROCESSING REQUEST FILE NUMBER 16348
26. DATE REVIEWED 19 Oct 2016		27. DATE FORWARDED TO 502 ISG/JAC
28. AUTHOR CONTACTED FOR RECOMMENDED OR NECESSARY CHANGES: <input checked="" type="checkbox"/> NO <input type="checkbox"/> YES If yes, give date. _____ <input type="checkbox"/> N/A		
29. COMMENTS <input checked="" type="checkbox"/> APPROVED <input type="checkbox"/> DISAPPROVED The presentation is approved.		
30. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER Rocky Calcote, PhD, Clinical Research Administrator	31. REVIEWER SIGNATURE CALCOTE ROCKY.D.1178245844 <small>Digitally signed by CALCOTE ROCKY.D.1178245844 DN: cn=US, o=US Government, ou=502 ISG/JAC, email=rocky.d.calcote@us.af.mil Date: 2016.10.19 11:38:03 -0500</small>	
32. DATE		
2nd ENDORSEMENT (502 ISG/JAC Use Only)		
33. DATE RECEIVED		34. DATE FORWARDED TO 59 MDW/PA
35. COMMENTS <input type="checkbox"/> APPROVED (In compliance with security and policy review directives.) <input type="checkbox"/> DISAPPROVED		
36. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER	37. REVIEWER SIGNATURE	
38. DATE		
3rd ENDORSEMENT (59 MDW/PA Use Only)		
39. DATE RECEIVED October 19, 2016		40. DATE FORWARDED TO 59 MDW/SGVU October 19, 2016
41. COMMENTS <input checked="" type="checkbox"/> APPROVED (In compliance with security and policy review directives.) <input type="checkbox"/> DISAPPROVED		
42. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER Kevin Iinuma, SSgt/E-5, 59 MDW Public Affairs	43. REVIEWER SIGNATURE IINUMA KEVIN MITSUGU 1296227 613 <small>Digitally signed by KEVIN MITSUGU IINUMA 1296227 DN: cn=US, o=US Government, ou=59 MDW, email=kevin.iinuma@us.af.mil Date: 2016.10.19 13:55:55 -0500</small>	
44. DATE October 19, 2016		
4th ENDORSEMENT (59 MDW/SGVU Use Only)		
45. DATE RECEIVED		46. SENIOR AUTHOR NOTIFIED BY PHONE OF APPROVAL OR DISAPPROVAL <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> COULD NOT BE REACHED <input type="checkbox"/> LEFT MESSAGE
47. COMMENTS <input type="checkbox"/> APPROVED <input type="checkbox"/> DISAPPROVED		
48. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER	49. REVIEWER SIGNATURE	
50. DATE		